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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/074,978

Applicant(s)

GUO ET AL.

Examiner

David J Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-77 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Application***

- [1]** Claims 1-77 are pending in the application.
- [2]** Applicant's amendment to the specification, filed October 11, 2002, is acknowledged.
- [3]** Receipt of a computer readable form of the sequence listing, a paper copy thereof, and a statement of their sameness, filed January 07, 2003, is acknowledged.
- [4]** Receipt of information disclosure statements filed October 10, 2003 and September 18, 2002, is acknowledged.
- [5]** Due to the numerous provisional applications to which the instant application claims priority under 35 USC 119(e), the examiner requests that applicants indicate which, if any, provisional application(s) disclose(s) the elected invention.

### ***Oath/Declaration***

- [6]** The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: There is no signature and date for inventor Yi Liu as required by 37 CFR 1.63.

### ***Election/Restrictions***

- [7]** Restriction to one of the following inventions is required under 35 U.S.C. 121:

Art Unit: 1652

- I. Claims 1-4, 29, and 32, drawn to an isolated polypeptide, a pharmaceutical composition, and a kit, classified in class 514, subclass 2.
- II. Claims 5-14, 30, and 33, drawn to an isolated nucleic acid, a vector, a cell, a pharmaceutical composition, and a kit, classified in class 514, subclass 44.
- III. Claims 15-17, 31, and 34, drawn to an antibody, a pharmaceutical composition, and a kit, classified in class 530, subclass 387.9.
- IV. Claims 57-58, drawn to a peroxisome proliferator-activated receptor gamma receptor ligand, classified in class 514, subclass 789.
- V. Claim 18, drawn to a method for determining the presence or amount of a polypeptide, classified in class 435, subclass 7.1.
- VI. Claim 19, drawn to a method for determining the presence or amount of a nucleic acid, classified in class 435, subclass 6.
- VII. Claim 20, drawn to a method of identifying an agent that binds to a polypeptide, classified in class 435, subclass 7.1.
- VIII. Claim 21, drawn to a method for identifying an agent that modulates the expression or activity of a polypeptide, classified in class 435, subclass 7.1.
- IX. Claim 22, drawn to a method for modulating the activity of a polypeptide, classified in class 530, subclass 350.

Art Unit: 1652

- X. Claims 23-24, drawn to a method of treating or preventing a NOVX-associated disorder by administering a polypeptide, classified in class 514, subclass 2.
- XI. Claims 25-26, drawn to a method of treating or preventing a NOVX-associated disorder by administering a polynucleotide, classified in class 514, subclass 44.
- XII. Claims 27-28, drawn to a method of treating or preventing a NOVX-associated disorder by administering an antibody, classified in class 424, subclass 130.1.
- XIII. Claim 35, drawn to the use of a therapeutic in the manufacture of a medicament, wherein said therapeutic is a polypeptide, classified in class 514, subclass 2.
- XIV. Claim 35, drawn to the use of a therapeutic in the manufacture of a medicament, wherein said therapeutic is a nucleic acid, classified in class 514, subclass 44.
- XV. Claim 35, drawn to the use of a therapeutic in the manufacture of a medicament, wherein said therapeutic is an antibody, classified in class 424, subclass 130.1.
- XVI. Claims 36-37, drawn to a method for screening for a modulator of activity or of latency or predisposition to a NOVX-associated disorder, classified in class 435, subclass 7.1.

- XVII. Claim 38, drawn a method for determining the presence of or predisposition to a disease associated with altered levels of a polypeptide, classified in class 435, subclass 7.1.
- XVIII. Claim 39, drawn a method for determining the presence of or predisposition to a disease associated with altered levels of a nucleic acid, classified in class 435, subclass 6.
- XIX. Claim 40, drawn to a method of treating a pathological state in a mammal by administering a polypeptide, classified in class 514, subclass 2.
- XX. Claim 41, drawn to a method of treating a pathological state in a mammal by administering an antibody, classified in class 514, subclass 139.1.
- XXI. Claims 42-50, drawn to a method of treating a disorder in a subject by administering a compound that decreases IL-8 expression or activity, classified in class 514, subclass 789.
- XXII. Claims 51-56 and 59-66, drawn to a method of identifying a ligand for the peroxisome proliferator-activated receptor gamma receptor and a method of identifying a therapeutic agent, classified in class 435, subclass 7.1.
- XXIII. Claim 67, drawn to a method of diagnosing or determining the susceptibility to clear cell renal carcinoma, classified in class 435, subclass 7.1.
- XXIV. Claims 68-71, drawn to a method of treating a renal disorder in a subject, classified in class 514, subclass 789.

XXV. Claim 72, drawn to a method of assessing the efficacy of a treatment of a kidney disorder, classified in class 435, subclass 7.1.

XXVI. Claim 73, drawn to a method of diagnosing or determining the susceptibility to an inflammatory disorder, classified in class 435, subclass 7.1.

XXVII. Claims 74-76, drawn to a method of treating an inflammatory disorder in a subject by administering an agent that decreases the expression or activity of ARP, classified in class 514, subclass 789.

XXVIII. Claim 77, drawn to a method of assessing the efficacy of a treatment of an inflammatory disorder, classified in class 435, subclass 7.1.

**[8]** If applicant should elect the invention of Group I, V, VII, VIII, IX, X, XIII, XVI, XVII, or XIX, restriction to one of the following is also required under 35 USC 121.

- a) The polypeptide of SEQ ID NO:2.
- b) The polypeptide of SEQ ID NO:4.
- c) The polypeptide of SEQ ID NO:6.
- d) The polypeptide of SEQ ID NO:8.
- e) The polypeptide of SEQ ID NO:10.
- f) The polypeptide of SEQ ID NO:12.
- g) The polypeptide of SEQ ID NO:14.
- h) The polypeptide of SEQ ID NO:16.
- i) The polypeptide of SEQ ID NO:18.

- j) The polypeptide of SEQ ID NO:20.
- k) The polypeptide of SEQ ID NO:22.
- l) The polypeptide of SEQ ID NO:24.
- m) The polypeptide of SEQ ID NO:26.
- n) The polypeptide of SEQ ID NO:28.
- o) The polypeptide of SEQ ID NO:30.
- p) The polypeptide of SEQ ID NO:32.
- q) The polypeptide of SEQ ID NO:34.
- r) The polypeptide of SEQ ID NO:36.
- s) The polypeptide of SEQ ID NO:38.
- t) The polypeptide of SEQ ID NO:40.
- u) The polypeptide of SEQ ID NO:42.
- v) The polypeptide of SEQ ID NO:44.
- w) The polypeptide of SEQ ID NO:46.
- x) The polypeptide of SEQ ID NO:48.
- y) The polypeptide of SEQ ID NO:50.
- z) The polypeptide of SEQ ID NO:52.
- aa)The polypeptide of SEQ ID NO:54.
- bb)The polypeptide of SEQ ID NO:56.
- cc)The polypeptide of SEQ ID NO:58.
- dd)The polypeptide of SEQ ID NO:60.
- ee)The polypeptide of SEQ ID NO:62.



- ff) The polypeptide of SEQ ID NO:64.
- gg)The polypeptide of SEQ ID NO:66.
- hh)The polypeptide of SEQ ID NO:68.
- ii) The polypeptide of SEQ ID NO:70.
- jj) The polypeptide of SEQ ID NO:72.
- kk)The polypeptide of SEQ ID NO:74.
- ll) The polypeptide of SEQ ID NO:76.
- mm) The polypeptide of SEQ ID NO:78.
- nn)The polypeptide of SEQ ID NO:80.
- oo)The polypeptide of SEQ ID NO:82.
- pp)The polypeptide of SEQ ID NO:84.
- qq)The polypeptide of SEQ ID NO:86.
- rr) The polypeptide of SEQ ID NO:88.
- ss)The polypeptide of SEQ ID NO:90.
- tt) The polypeptide of SEQ ID NO:92.
- uu)The polypeptide of SEQ ID NO:94.
- vv) The polypeptide of SEQ ID NO:96.
- ww) The polypeptide of SEQ ID NO:98.
- xx)The polypeptide of SEQ ID NO:100.
- yy)The polypeptide of SEQ ID NO:102.
- zz)The polypeptide of SEQ ID NO:104.
- aaa) The polypeptide of SEQ ID NO:106.

Art Unit: 1652

bbb) The polypeptide of SEQ ID NO:108.

ccc) The polypeptide of SEQ ID NO:110.

ddd) The polypeptide of SEQ ID NO:112.

**[9]** If applicant should elect the invention of Group II, VI, VIII, IX, XI, XIV, or XVIII, restriction to one of the following is also required under 35 USC 121.

eee) A polynucleotide encoding SEQ ID NO:2 including SEQ ID NO:1.

fff) A polynucleotide encoding SEQ ID NO:4 including SEQ ID NO:3.

ggg) A polynucleotide encoding SEQ ID NO:6 including SEQ ID NO:5.

hhh) A polynucleotide encoding SEQ ID NO:8 including SEQ ID NO:7.

iii) A polynucleotide encoding SEQ ID NO:10 including SEQ ID NO:9.

jjj) A polynucleotide encoding SEQ ID NO:12 including SEQ ID NO:11.

kkk) A polynucleotide encoding SEQ ID NO:14 including SEQ ID NO:13.

lll) A polynucleotide encoding SEQ ID NO:16 including SEQ ID NO:15.

mmm) A polynucleotide encoding SEQ ID NO:18 including SEQ ID NO:17.

nnn) A polynucleotide encoding SEQ ID NO:20 including SEQ ID NO:19.

ooo) A polynucleotide encoding SEQ ID NO:22 including SEQ ID NO:21.

ppp) A polynucleotide encoding SEQ ID NO:24 including SEQ ID NO:23.

qqq) A polynucleotide encoding SEQ ID NO:26 including SEQ ID NO:25.

rrr) A polynucleotide encoding SEQ ID NO:28 including SEQ ID NO:27.

sss) A polynucleotide encoding SEQ ID NO:30 including SEQ ID NO:29.

ttt) A polynucleotide encoding SEQ ID NO:32 including SEQ ID NO:31.

uuu) A polynucleotide encoding SEQ ID NO:34 including SEQ ID NO:33.

Art Unit: 1652

- vvv) A polynucleotide encoding SEQ ID NO:36 including SEQ ID NO:35.
- www) A polynucleotide encoding SEQ ID NO:38 including SEQ ID NO:37.
- xxx) A polynucleotide encoding SEQ ID NO:40 including SEQ ID NO:39.
- yyy) A polynucleotide encoding SEQ ID NO:42 including SEQ ID NO:41.
- zzz) A polynucleotide encoding SEQ ID NO:44 including SEQ ID NO:43.
- aaaa) A polynucleotide encoding SEQ ID NO:46 including SEQ ID NO:45.
- bbbb) A polynucleotide encoding SEQ ID NO:48 including SEQ ID NO:47.
- cccc) A polynucleotide encoding SEQ ID NO:50 including SEQ ID NO:49.
- dddd) A polynucleotide encoding SEQ ID NO:52 including SEQ ID NO:51.
- eeee) A polynucleotide encoding SEQ ID NO:54 including SEQ ID NO:53.
- ffff) A polynucleotide encoding SEQ ID NO:56 including SEQ ID NO:55.
- gggg) A polynucleotide encoding SEQ ID NO:58 including SEQ ID NO:57.
- hhhh) A polynucleotide encoding SEQ ID NO:60 including SEQ ID NO:59.
- iiii) A polynucleotide encoding SEQ ID NO:62 including SEQ ID NO:61.
- jjjj) A polynucleotide encoding SEQ ID NO:64 including SEQ ID NO:63.
- kkkk) A polynucleotide encoding SEQ ID NO:66 including SEQ ID NO:65.
- llll) A polynucleotide encoding SEQ ID NO:68 including SEQ ID NO:67.
- mmmm) A polynucleotide encoding SEQ ID NO:70 including SEQ ID NO:69.
- nnnn) A polynucleotide encoding SEQ ID NO:72 including SEQ ID NO:71.
- oooo) A polynucleotide encoding SEQ ID NO:74 including SEQ ID NO:73.
- pppp) A polynucleotide encoding SEQ ID NO:76 including SEQ ID NO:75.
- qqqq) A polynucleotide encoding SEQ ID NO:78 including SEQ ID NO:77.

Art Unit: 1652

- rrrr) A polynucleotide encoding SEQ ID NO:80 including SEQ ID NO:79.
- ssss) A polynucleotide encoding SEQ ID NO:82 including SEQ ID NO:81.
- tttt) A polynucleotide encoding SEQ ID NO:84 including SEQ ID NO:83.
- uuuu) A polynucleotide encoding SEQ ID NO:86 including SEQ ID NO:85.
- vvvv) A polynucleotide encoding SEQ ID NO:88 including SEQ ID NO:87.
- www) A polynucleotide encoding SEQ ID NO:90 including SEQ ID NO:89.
- xxxx) A polynucleotide encoding SEQ ID NO:92 including SEQ ID NO:91.
- yyyy) A polynucleotide encoding SEQ ID NO:94 including SEQ ID NO:93.
- zzzz) A polynucleotide encoding SEQ ID NO:96 including SEQ ID NO:95.
- aaaaa) A polynucleotide encoding SEQ ID NO:98 including SEQ ID NO:97.
- bbbbb) A polynucleotide encoding SEQ ID NO:100 including SEQ ID NO:99.
- ccccc) A polynucleotide encoding SEQ ID NO:102 including SEQ ID NO:101.
- dddd) A polynucleotide encoding SEQ ID NO:104 including SEQ ID NO:103.
- eeee) A polynucleotide encoding SEQ ID NO:106 including SEQ ID NO:105.
- ffff) A polynucleotide encoding SEQ ID NO:108 including SEQ ID NO:107.
- ggggg) A polynucleotide encoding SEQ ID NO:110 including SEQ ID NO:109.
- hhhhh) A polynucleotide encoding SEQ ID NO:112 including SEQ ID NO:111.

**[10]** If applicant should elect the invention of Group III, V, XII, XV, or XX, restriction to one of the following is also required under 35 USC 121.

- iiii) An antibody that binds the polypeptide of SEQ ID NO:2.
- jjjj) An antibody that binds the polypeptide of SEQ ID NO:4.
- kkkkk) An antibody that binds the polypeptide of SEQ ID NO:6.

Art Unit: 1652

- lllll) An antibody that binds the polypeptide of SEQ ID NO:8.
- mmmmm) An antibody that binds the polypeptide of SEQ ID NO:10.
- nnnnn) An antibody that binds the polypeptide of SEQ ID NO:12.
- ooooo) An antibody that binds the polypeptide of SEQ ID NO:14.
- ppppp) An antibody that binds the polypeptide of SEQ ID NO:16.
- qqqqq) An antibody that binds the polypeptide of SEQ ID NO:18.
- rrrrr) An antibody that binds the polypeptide of SEQ ID NO:20.
- sssss) An antibody that binds the polypeptide of SEQ ID NO:22.
- ttttt) An antibody that binds the polypeptide of SEQ ID NO:24.
- uuuuu) An antibody that binds the polypeptide of SEQ ID NO:26.
- vvvvv) An antibody that binds the polypeptide of SEQ ID NO:28.
- wwwww) An antibody that binds the polypeptide of SEQ ID NO:30.
- xxxxx) An antibody that binds the polypeptide of SEQ ID NO:32.
- yyyyy) An antibody that binds the polypeptide of SEQ ID NO:34.
- zzzzz) An antibody that binds the polypeptide of SEQ ID NO:36.
- aaaaaa) An antibody that binds the polypeptide of SEQ ID NO:38.
- bbbbbb) An antibody that binds the polypeptide of SEQ ID NO:40.
- cccccc) An antibody that binds the polypeptide of SEQ ID NO:42.
- dddddd) An antibody that binds the polypeptide of SEQ ID NO:44.
- eeeeee) An antibody that binds the polypeptide of SEQ ID NO:46.
- ffffff) An antibody that binds the polypeptide of SEQ ID NO:48.
- gggggg) An antibody that binds the polypeptide of SEQ ID NO:50.

Art Unit: 1652

- hhhhhh) An antibody that binds the polypeptide of SEQ ID NO:52.
- iiiiii) An antibody that binds the polypeptide of SEQ ID NO:54.
- jjjjjj) An antibody that binds the polypeptide of SEQ ID NO:56.
- kkkkkk) An antibody that binds the polypeptide of SEQ ID NO:58.
- llllll) An antibody that binds the polypeptide of SEQ ID NO:60.
- mmmmmm) An antibody that binds the polypeptide of SEQ ID NO:62.
- nnnnnn) An antibody that binds the polypeptide of SEQ ID NO:64.
- oooooo) An antibody that binds the polypeptide of SEQ ID NO:66.
- pppppp) An antibody that binds the polypeptide of SEQ ID NO:68.
- qqqqqq) An antibody that binds the polypeptide of SEQ ID NO:70.
- rrrrrr) An antibody that binds the polypeptide of SEQ ID NO:72.
- ssssss) An antibody that binds the polypeptide of SEQ ID NO:74.
- tttttt) An antibody that binds the polypeptide of SEQ ID NO:76.
- uuuuuu) An antibody that binds the polypeptide of SEQ ID NO:78.
- vvvvvv) An antibody that binds the polypeptide of SEQ ID NO:80.
- wwwwww) An antibody that binds the polypeptide of SEQ ID NO:82.
- xxxxxx) An antibody that binds the polypeptide of SEQ ID NO:84.
- yyyyyy) An antibody that binds the polypeptide of SEQ ID NO:86.
- zzzzzz) An antibody that binds the polypeptide of SEQ ID NO:88.
- aaaaaaa) An antibody that binds the polypeptide of SEQ ID NO:90.
- bbbbbbb) An antibody that binds the polypeptide of SEQ ID NO:92.
- ccccccc) An antibody that binds the polypeptide of SEQ ID NO:94.

Art Unit: 1652

ddddddd) An antibody that binds the polypeptide of SEQ ID NO:96.

eeeeeee) An antibody that binds the polypeptide of SEQ ID NO:98.

ffffff) An antibody that binds the polypeptide of SEQ ID NO:100.

ggggggg) An antibody that binds the polypeptide of SEQ ID NO:102.

hhhhhhh) An antibody that binds the polypeptide of SEQ ID NO:104.

iiiiiii) An antibody that binds the polypeptide of SEQ ID NO:106.

jjjjjjj) An antibody that binds the polypeptide of SEQ ID NO:108.

kkkkkkk) An antibody that binds the polypeptide of SEQ ID NO:110.

lllllll) An antibody that binds the polypeptide of SEQ ID NO:112.

**[11]** The inventions are distinct, each from the other because:

**[12]** The polypeptides of Groups a)-ddd) are structurally distinct and no single polypeptide of Groups a)-ddd) would render any of the others obvious to one of ordinary skill in the art; the polynucleotides of Groups eee)-hhhhh) are structurally distinct and no single polynucleotide of Groups eee)-hhhhh) would render any of the others obvious to one of ordinary skill in the art; and the antibodies of Groups iiiii)-lllllll) are structurally distinct and no single antibody of Groups iiiii)-lllllll) would render any of the others obvious to one of ordinary skill in the art.

**[13]** The polypeptide of Group I, the nucleic acid of Group II, the antibody of Group III, and ligand of Group IV each comprises a chemically unrelated structure capable of separate manufacture, use and effect. The polynucleotide of Group II has other utility besides encoding polypeptides such as being used as a hybridization probe and the

Art Unit: 1652

polypeptide of Group I can be made by another method such as purification from the natural source or by chemical synthesis.

**[14]** The polypeptide of Group I is unrelated to the method(s) of Groups VI, XI, XII, XIV, XV, XVIII, and XX-XXVIII as it is neither used nor made by the method(s) of Groups VI, XI, XII, XIV, XV, XVIII, and XX-XXVIII.

**[15]** The polypeptide of Group I and the methods of Groups V, VII-X, XIII, XVI-XVII, and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used as an antigen in the production of antibodies.

**[16]** The polynucleotide of Group II is unrelated to the method(s) of Groups VII, X, XII-XIII, XV-XVII, and XIX-XXVIII as it is neither used nor made by the method(s) of Groups VII, X, XII-XIII, XV-XVII, and XIX-XXVIII.

**[17]** The polynucleotide of Group II and the methods of Groups VI, VIII-IX, XI, XIV, and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group I can be used for protein expression.



Art Unit: 1652

**[18]** The antibody of Group III is unrelated to the method(s) of Groups VI-XI, XIII-XIV, XVI-XIX, and XXI-XXVIII as it is neither used nor made by the method(s) of Groups VI-XI, XIII-XIV, XVI-XIX, and XXI-XXVIII.

**[19]** The antibody of Group III and the methods of Groups V, XII, XV, and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used as an affinity reagent in the purification of a polypeptide.

**[20]** The ligand of Group IV is unrelated to the method(s) of Groups V-XXI and XXIII-XXVIII as it is neither used nor made by the method(s) of Groups V-XXI and XXIII-XXVIII.

**[21]** The ligand of Group IV and the method of Group XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ligand of Group IV can be used as an affinity reagent in the purification of a peroxisome proliferator-activated receptor gamma receptor polypeptide.

**[22]** The methods of Groups V-XXVIII are independent as they comprise different steps, utilize different products, and yield different results.

***Rejoinder***

**[23]** The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Conclusion***

**[24]** MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups a)-IIIIII) and I-XXVIII are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature search requiring a different text and/or sequence search for each Group and thus, co-examination of the inventions of Groups a)-IIIIII) and I-XXVIII would require a serious burden on the examiner.

**[25]** It is noted that the claims will be examined only to the extent they read on the elected subject matter.

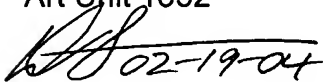
Art Unit: 1652

**[26]** Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**[27]** Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman  
Patent Examiner  
Art Unit 1652



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